DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Climb Medical Systems, Inc.
% Kenneth Wade
International Marketing Manager
Senri Life Science Center Bldg. 10F
1-4-2 Shinsenri Higashimachi
TOYONAKA-SHI OSAKA 560-0082
JAPAN

August 29, 2014

Re: K141364
Trade/Device Name: Climb Mammography Viewer Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: August 14, 2014
Received: August 18, 2014

Dear Mr. Wade:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141364

Device Name
Climb Mammography Viewer Software

Indications for Use *(Describe)*
Climb-Mammography Viewer is intended to be used by radiologists for the reading, manipulation and interpretation of DICOM digital breast images including mammography. Radiologists are able to select, display, manipulate, quantify, mark-up, print and exchange images.

Lossy compressed mammographic images must not be reviewed for primary image interpretations. Images may only be interpreted using an FDA cleared display that meets technical specifications reviewed and accepted by FDA for digital mammography. All images must conform to regulatory requirements. Image quality must conform to applicable quality guidance.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

(as required by 21 CFR 807.92)

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Date Prepared	May 21, 2014

Trade Name	Climb Mammography Viewer
Common Name	Display
Classification Name	Picture Archiving and Communication System
Class	Class II, Special Controls
Regulation Number	21 CFR 892.2050
Product Code	LLZ: Radiological Image Processing System

Predicate Devices	Cedara I-SoftView / Cedara-I ReadMammo	K040468	Cedara Software Corporation
	WorkstationOne™ Breast Imaging Workstation	K073272	Three Palm Software, LLC

Description	Climb Mammography Viewer Software is breast imaging workstation software. The system allows for the display and manipulation of images that have been obtained from PACS or modalities. Source images are obtained as the recipient of push data for the images. The system can also automatically open images and the corresponding reporting page. The product includes features that allow the qualified medical professional to view patient medical images

Indications and Intended Use	Climb Mammography Viewer is intended to be used by radiologists for the reading, manipulation and interpretation of DICOM digital breast images including mammography. Radiologists are able to select, display, manipulate, quantify, mark-up, print and exchange images. Lossy compressed mammographic images must not be reviewed for primary image interpretations. Images may only be interpreted using an FDA cleared display that meets technical specifications reviewed and accepted by FDA for digital mammography. All images must conform to regulatory requirements. Image quality must conform to applicable quality guidance.

Technological Characteristics and	Documentation was provided to demonstrate that the Climb Mammography-Viewer is substantially equivalent to the predicates Cedara I-SoftView / Cedara-

Substantial Equivalence	I ReadMam (K040468) and WorkstationOne™ Breast Imaging Workstation (K073272). The Climb Mammography-Viewer device is substantially equivalent to the predicate devices in intended use, indications for use, technological characteristics, and labeling.

Performance Data	The potential hazards have been evaluated and controlled through a Risk Management Plan. All software verification and validation testing met or exceeded the requirements as established by the test protocol and applicable standards. The results demonstrated that the Subject device presents no new worst case for performance testing and the Subject device was therefore found to be substantially equivalent to the Predicate.

Conclusion	Based on the indications for use, technological characteristics, and comparison to predicate devices, the Subject Climb Mammography-Viewer has been shown to be substantially equivalent to legally marketed predicate devices, and safe and effective for its intended use.